



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL -8456-01
June 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Laura Simons, M.D.
Lead Interpreting Physician
Lake Cumberland Medical Associates
350 Hospital Way
Somerset, KY 42503

Facility I.D.#: 136648

Dear Dr. Simons:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on June 6, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

Medical Records and Mammography Reports— 21 CFR 900.12(c)(1)(iv)(A)-(E) & (v)

Five of ten random interpreting physician mammography reports did not contain the required overall final assessment of findings. The inspection found five mammography reports of films read by [REDACTED] were without the required final assessment languages. The five mammography reports each appeared to be negative impression, however these reports were without any of the required final assessment languages.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection.

In addition, your response should address the Level 2 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance item is:

Personnel- Medical Physicists 21 CFR 900.12 (a)(3)(iii)(A)

Your facility failed to produce documents demonstrating that [REDACTED] a medical physicist meets the requirement of having taught or completed a minimum of fifteen (15) continuing education units in mammography in thirty six (36) months.

Because these conditions may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, these represent violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other items listed in your June 6, 2001 inspection report identified, as Level 3 should also be corrected. We will verify corrections on these items during our next inspection. You are not required to address the Level 3 items in your written response.

It is necessary for you to act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

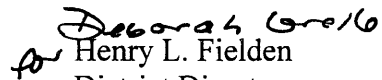
Also, please send a copy to the State radiation control office:

Mr. Steve Mays
Kentucky Radiation Control
275 E. Main St., Mail Stop 2E-D
Frankfort, KY 40621

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,


Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/SMays

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